

PROJECT SHEET

SUBCOMMITTEE: Regulatory Capacity Building

PROJECT TITLE: **Electronic Submissions**
- **Electronic Review Templates for Data Evaluation Reports**
- **Electronic Submissions and Review**
- **Harmonize Assembly of Electronic Submissions**

PROJECT ID: RC06-96-1205

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PROJECT DATES: Start: Summer 1996
Revision: December 2005

UPDATE: See Work Plan activities

GOAL: To achieve operating efficiencies in pesticide regulation through the promotion, facilitation and international harmonization of the electronic submission process, including data delivery, review, exchange, storage and visibility. To harmonize and implement the standard templates using the Extensible Markup Language (XML) schemas proposed to improve our review of study data.

PROJECT DESCRIPTION:

To establish a process for accepting and reviewing submissions electronically with the capacity to exchange data with stakeholders involved in the regulatory process.

BACKGROUND/RATIONALE:

Various initiatives in the use of information technologies are undertaken to achieve operating efficiencies in the regulation of pesticides. The majority of these initiatives are conducted by individual countries that share the results with NAFTA partners in both government and industry. The initial NAFTA efforts were to consolidate and standardize study submission formats. Health Canada's Pest Management Regulatory Agency (PMRA) and United States Environmental Protection Agency (EPA) Office of Pesticide Programs (OPP) collaborated on other electronic submission efforts outside the scope of NAFTA. These efforts include the submission of electronic registration applications, full study data and other similar initiatives.

In September 2004, the EPA and Mexico attended a two-day technical work share session in Ottawa, hosted by the PMRA to exchange opportunities to leverage IT best practices. The PMRA and the EPA received three pilot joint review e-submissions in March-April 2004 indexed with the e-index tool announced in December 2003. For the PMRA, the benefits were immediate: the e-index has enabled the automation of the principal data entry process, which previously took three weeks of manual labour, and now, if properly populated, this process takes 1.5 hours. The PMRA will continue to encourage registrants to submit e-submissions using this method and share results with the EPA.

In November 2005, EPA visited PMRA to investigate ways in which EPA can leverage the PMRA's experience related to electronic submission and data standardization. This included the review of lessons learned in the development of the e-Index tool, PMRA's plans for future enhancements, and the assessment of emerging international standards (such as the NAFTA and OECD study evaluation templates). To the extent possible, EPA will design its own solutions based on similar concepts and technology to PMRA, with the goal of facilitating information exchange between the two agencies and increasing the registrants' efficiency in managing their submissions.

WORK PLAN

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GOAL	ACTIVITIES	TIMEFRAME
e-PRS—Access Management Module	PMRA —Allows information providers to manage their on-line accounts, passwords as well as the assignment of rights and privileges to others as necessary based on business needs. DONE	April 2005
e-PRS—e-Index Tool	PMRA —Supports the On-line Delivery Modules by assisting the user in creating an Index file, in XML format, which fully describes each document being e-submitted as part of an electronic submission. DONE	September 2005
Workbook 5.0 (Document Management Module)	PMRA —Supports new requirements of <i>Pest Control Products Act</i> . (Confidential Business Information and transparency). Delivery coincided with release of e-Index builder to industry. DONE	October 2005
Information Sharing	OPP/PMRA —Meet to review existing applications and share requirements for the submission of XML schema. DONE	November 2005
Gather Requirements for Electronic Submission and Review Formats	OPP/PMRA —Work together to formulate an approach to handling e-submitted study summaries and registration applications. The PMRA has created a series of pilots with registrants and reviewers that allowed industry to assemble large data submissions in PDF with XML of the index data. The OPP will now take the lead in continuing these efforts. The objective is to establish an electronic data formatting standard that is practical and achievable for registrants and meeting the functional requirements of Agency’s staff responsible for analyzing studies and preparing review documents.	May 2006
e-PRS—Adverse Effects Reporting Module	PMRA —Adverse Effects Reporting Module	October 2006
e-PRS—Application for New or Amended Registration Module	PMRA —Application for New or Amended Registration Module	November 2006

GOAL	ACTIVITIES	TIMEFRAME
Test receipt and processing of electronic indices and study summaries	<p>OPP— Develop a pilot that will use a standardize format and XML schema for a submission package to EPA, using PMRA’s e-Index tool as a model.</p> <ol style="list-style-type: none"> 1. Develop a consumption engine for XML data and e-submission files. 2. Devise a plan for storing the incoming e-submission data. 3. Devise a plan for storing the incoming files as documents within PRISM’s document management repository. 4. Develop a communication strategy to solicit registrant participation in the pilot activities. 	August 2006
Undertake communication activities to promote the use of standardized electronic formats by industry	OPP/PMRA —Joint development of a communication plan	In planning
e-PRS—National Pest Sales Reporting Module	PMRA —National Pest Sales Reporting Module	In planning
Evaluate the finalized study templates	OPP —Determine how the receipt of study summaries in electronic format will initiate changes to the internal business processes of the science and regulatory divisions, as well as the front-end processing team.	Ongoing
Determine the requirements for a technical solution to process incoming studies in the format of the harmonized templates.	OPP —Determine the requirements for processing incoming registration applications in electronic format.	Ongoing
Develop a methodology for promoting the use of the harmonized templates amongst industry members.	OPP —This will likely include the development of a technical solution that facilitates data entry of registration or study information in the prescribed formats.	Ongoing

GOAL	ACTIVITIES	TIMEFRAME
Address legal and policy issues related to the acceptance of electronic documentation.	OPP —Determine whether an electronic application or study can be considered the legally referential copy of the document.	Ongoing
Harmonized electronic evaluation templates continue to be refined under a NAFTA project.	OPP —The OPP posted Study Profile templates that mirror the evaluation templates. Data submitters are encouraged to submit studies using these templates to facilitate use of the evaluation templates.	Ongoing
Refine technical specifications for submissions as well as guidance on formatting study reports, full submissions, supplemental files and review aids as well as in-processing steps.	OPP —Share results with the PMRA and industry.	Ongoing
Evaluate electronic data submission and review efforts; building on experiences to refine.	OPP —Share results with the PMRA and industry.	Ongoing
Share North American experiences with electronic submission and review with the European Community and the Organisation for Economic Co-operation and Development (OECD).	OPP —Share results of process and standard harmonization.	Ongoing
Explore other electronic submission and review opportunities	OPP/PMRA —Formed work teams to explore other uses of information technology to share experiences. The potential for the use of XML as a data submission format is being explored. The PMRA and the OPP work teams will share the results of these efforts to promote further harmonization of processes and work sharing. The PMRA and the OPP are actively participating in the current OECD Template pilot IT subcommittee looking at the use of XML for template formats for global interchange.	Ongoing

GOAL	ACTIVITIES	TIMEFRAME
<p>Increase involvement of industry in Electronic Submission and Review Project</p>	<p>OPP—Establish and maintain process for communications of activities among the PMRA, the EPA and industry as represented by the industry group. Continue to explore the use of technologies for forms and labels.</p>	<p>Ongoing</p>